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| 10/072,525      | 02/05/2002  | Karla Robotti        | 10011206            | 2898             |

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EXAMINER

NGUYEN, QUANG

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1636

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

10/072,525

### Applicant(s)

ROBOTTI, KARLA

### Examiner

Quang Nguyen, Ph.D.

### Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9, 14-21, 24 and 26-59 is/are pending in the application.
- 4a) Of the above claim(s) 57 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44 is/are allowed.
- 6) ☒ Claim(s) 9, 14, 15, 28-32, 37-40, 45-56, 58 and 59 is/are rejected.
- 7) ☒ Claim(s) 1-6, 16-21, 24, 26-27, 33-36 and 41-43 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's amendment filed on 5/20/04 has been entered.

Claims 1-6, 9, 14-21, 24, 26-59 are pending in the present application.

This application contains claim 57 drawn to an invention nonelected without traverse in the Response to Election/Restriction filed on 11/17/03. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Accordingly, amended claims 1-6, 9, 14-21, 24 and 26-56 and 58-59 are examined on the merits herein.

#### ***Response to Applicant's amendment***

The rejection under 35 U.S.C. 102(e) by Liu et al. (US 6,303,290) is withdrawn in light of Applicant's amendment.

The rejection under 35 U.S.C. 102(b) by Dunn et al. (US 5,200,334) is withdrawn in light of Applicant's amendment.

The rejection under 35 U.S.C. 103(a) by Dunn et al. (US 5,200,334) or Liu et al. (US 6,303,290) in view of Avnir et al. (US 5,300,564) is withdrawn.

#### ***Claim Objections***

Claims 1, 9 and their dependent claims are objected to because of the term "in step (b)". This is because the steps of the recited methods are not labeled. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 14-15, 28-32 and 37-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new ground of rejection necessitated by Applicant's amendment.**

In claim 9 and its dependent claims, there is no linkage between the method steps being recited with the preamble "immobilizing a biological molecule in a porous inorganic matrix incorporated into a microanalytical device". Therefore, the metes and bounds of the claims are not clearly determined.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended claims 9, 14-15, 28-32 and 37-40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. (U.S. Patent No. 5,200,334) in view of Reetz et al. (Biotechnology and Bioengineering, Vol. 9:527-534, 1996) for the same reasons already set forth in the previous Office Action mailed on 2/24/04 (pages 12-13).

### ***Response to Arguments***

Applicant's argument related to the above rejection in the Amendment filed on 5/20/04 (pages 15-16) have been fully considered, but it is respectfully found to be unpersuasive.

Applicant argues mainly that neither Dunn nor Reetz teaches or suggests forming a sol *in situ* in a microanalytical device.

Please note that the rejection is maintained because the combined teachings of Dunn and Reetz have the same method steps as those recited in the amended claim 9. Furthermore, the term "the porous inorganic material is formed *in situ*" includes the the formation of a porous inorganic material in any reaction vessel.

Accordingly, amended claims 9, 14-15, 28-32 and 37-40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. in view of Reetz et al. for the reasons of record.

Claims 45-56 and 58-59 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al. (U.S. Patent No. 5,200,334; IDS) in view of Avnir et al. (U.S. Patent No. 5,300,564; IDS), Swedberg et al. (U.S. Patent No. 6,240,790) and Freeman et al. (U.S. Patent No. 6,194,900) for the same reasons already set forth in the previous Office Action mailed on 2/24/04 (pages 13-17).

### ***Response to Arguments***

Applicant's arguments related to the above rejection in the Amendment filed on 5/20/04 (pages 16-18) have been fully considered, but they are respectfully found to be unpersuasive.

Applicant argues mainly that the combined teachings of Dunn and Avnir do not teach or suggest methods of the presently claimed invention for preparing and using a microanalytical device having a sol-gel comprising entrapped biological molecule, and that the teachings of Swedberg and Freeman do not remedy this deficiency. Applicant further argues that the mere fact that Dunn touts the benefits of its sol-gel and that Avnir describes the suitability of sol-gels enzymatic column chromatography is insufficient to suggest to one of skill in the art that the teachings could be modified for use in microanalytical devices with a reasonable expectation of success.

Please note that Dunn clearly teaches that encapsulated or entrapped enzymes are used as micro-catalysts and analytical devices of very high sensitivity, and in contrast to the membrane systems known in the art, encapsulated enzymes in the sol-

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gel process is far more reliable, less cumbersome and is significantly easier to miniaturize (col. 1, lines 15-36). Avnir further teaches that doped sol-gel glasses can be crushed to be used as support for all chromatographic purposes including liquid, gas, thin layer as well as enzymatic chromatography for qualitative and for quantitative analysis (col. 3, lines 29-61), while both Swedberg and Freeman already disclose micro-devices for a high through-put analysis of small and/or macromolecular solutes in biological fluids. An ordinary skilled artisan would have been motivated to combine the above teachings for achieving a high throughput sample processing and analysis as well as a fast time-to-result analysis of biological liquids in a truly integrated fashion, especially encapsulated enzymes in the sol-gel can be miniaturized and can be used as support for all chromatographic purposes.

It is not clear why one would not reasonably expect the combined teachings of Dunn, Avnir, Swedberg and Freeman to be successful. Please also note that Applicant has not even actually made or prepared any micro-analytical device comprising a sol-gel comprising an entrapped biological molecule.

Accordingly, the instant claims stand rejected for the reasons of record.

### ***Conclusion***

***Claim 44 is allowable.***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP



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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

**To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.**

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service

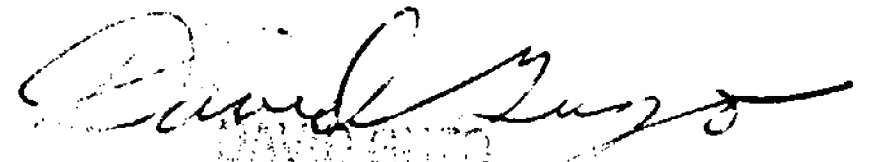


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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

*Quang Nguyen, Ph.D.*

  
DAVID S. SUSS  
PRIMARY EXAMINER